

Environmental Protection Agency

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transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(F), unless a new transfer agreement is submitted to the Agency.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

§ 152.99 Petitions to cancel registration.

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) *Grounds for petition.* (1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant's failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on compensation. The petitioner shall submit a copy of the agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure.

(iv) The applicant has failed to comply with the terms of an arbitration decision. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures

of this subpart has deprived him of the rights accorded him under FIFRA section 3(c)(1)(F). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has falsely or improperly claimed that a data gap existed at the time of his application.

(v) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) *Procedure for petition to the Agency—*(1) *Time for filing.* A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, the petitioner shall send a copy to the affected applicant or registrant by certified mail or by any other method that provides evidence of delivery. The affected applicant or registrant shall have 60 days from the date of receipt of the petition to submit written comments to the Agency.

(c) *Disposition of petitions.* The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or

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registrant that it intends to deny or cancel the registration of the product in support of which the data were cited. The affected applicant or registrant will have 15 days from the date of delivery of this notice to respond. If the Agency determines, after considering any response, that the affected applicant or registrant has acted in the ways described by paragraph (a)(1) of this section, the Agency will deny or cancel the registration without further hearing. Refer to FIFRA section 3(c)(1)(F)(ii). Denial or cancellation of a registration is a final Agency action.

(3) Except as provided in paragraph (c)(2) of this section, if the Agency determines that an applicant for registration of a product has acted in any way that deprives an original data submitter of rights under FIFRA section 3(c)(1)(F), the Agency will take steps to deny the application or cancel the registration, as appropriate. The procedures in FIFRA section 3(c)(6) or section 6(b) shall be followed. Denial or cancellation is a final Agency action.

(d) *Hearing.* Any hearing will be conducted in accordance with the procedures in 40 CFR part 164. The only matter for resolution at the hearing shall be whether the registrant failed to comply with the requirements and procedures of FIFRA section 3(c)(1)(F) or of this subpart, in the manner described by the petitioner. A decision following a hearing shall be final.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008; 79 FR 6826, Feb. 5, 2014]

Subpart F—Agency Review of Applications

SOURCE: 53 FR 15980, May 4, 1988, unless otherwise noted.

§ 152.100 Scope.

(a) The Agency will follow the procedures in this subpart for all applications for registration, except an application for registration of a pesticide that has been the subject of a previous Agency cancellation or suspension notice under FIFRA sec. 6.

(b) The Agency will follow the procedures of subpart D of part 164 of this chapter in evaluating any application

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for registration of a pesticide involving use of the pesticide in a manner that is prohibited by a suspension or cancellation order, to the extent required by subpart D of part 164.

§ 152.102 Publication.

The Agency will issue in the FEDERAL REGISTER a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the FEDERAL REGISTER a notice of issuance. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

§ 152.104 Completeness of applications.

The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. The Agency will review each application to determine whether it is complete. An application is incomplete if any pertinent item specified in § 152.50 has not been submitted, or has been incorrectly submitted (for example, data required by part 158, or part 161 of this chapter, as applicable, and not submitted in accordance with the requirements for format, claims of confidential business information, or flagging).

[72 FR 61028, Oct. 26, 2007]

§ 152.105 Incomplete applications.

The Agency will not begin or continue the review of an application that is incomplete. If the Agency determines that an application is incomplete or that further information is needed in order to complete the Agency's review, the Agency will notify the applicant of the deficiencies and allow the applicant 75 days to make corrections or additions to complete the application. If the applicant believes that the deficiencies cannot be corrected within 75 days, he must notify the Agency within those 75 days of the date on which he expects to complete the